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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,606	12/11/2003	Bei Chen	ABGENIX.058A	9342

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
11/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	10/734,606	CHEN ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,10-19,22-28,31-33,35-37 and 40-48* is/are pending in the application.

4a) Of the above claim(s) *10-19 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,25-28,31-33,35-37,40-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3, 5-7, 25-28, 31-33, 35-37 and 40-48 are under consideration.

2. In view of Applicants' amendment to the claims, the following rejections remain.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 5-7, 25-28, 31-33, 35-37, 40, 42, 43, 45, 46 and 48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US2003/0138417(of record) A1 as is evidenced by the SYNAGIS product information sheet (of record) in view of U.S. Pat. No. 5,580,856 (of record) for the reasons set forth in the office action mailed 2/26/07.

Applicants' arguments filed on 8/17/07 have been fully considered but they were not persuasive.

Applicants traversed the rejection based on that reference does not teach the currently amended limitation, "concentration of histidine is about 15mM and the concentration of arginine is about 15mM" and the combination of the reference is not obvious.

Contrary to Applicant's assertion, the '417 publication teaches the concentration of histidine is about 15mM ("about 30mM" of histidine, claim 2, in particular). The term "about" in the '417 publication and in the claimed invention broaden the concentration range to include the concentration ranges below or above the claimed 15mM and 30mM. As the overlapping concentration such as "about 20mM" are encompassed by both '417 publication and the claimed invention, the prima facie obviousness exists. Moreover, the optimization within the prior art condition or through routine experimentation is not considered to be inventive (MPEP 2144.05).

Furthermore, the concentration of arginine being about 15mM is also taught by the '856 patent. The use of arginine in concentration of about 0.5%-5% (col. 4, lines 30-50, in particular). Given the molecular weight of arginine being 174.2g/ml, 2.55% of arginine is equivalent to about 15mM.

In light of the discussion above, the combination of the references remains obvious.

5. Claims 1, 41, 44 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US2003/0138417(of record) in view of U.S. Pat. No. 5,580,856 (of record) and U.S. Pat. No. 4,849,352 (of record) for the reasons set forth in the office action mailed 2/26/07.

Applicants' arguments filed on 8/17/07 have been fully considered but they were not persuasive.

Applicants traversed the rejection based on that reference does not teach the currently amended limitation, "concentration of histidine is about 15mM and the concentration of arginine is about 15mM" and the combination of the reference is not obvious.

Contrary to Applicant's assertion, the '417 publication teaches the concentration of histidine is about 15mM ("about 30mM" of histidine, claim 2, in particular). The term "about" in the '417 publication and in the claimed invention broaden the concentration range to include the concentration ranges below or above the claimed 15mM and 30mM. As the overlapping concentration such as "about 20mM" are encompassed by both '417 publication and the claimed invention, the prima facie obviousness exists. Moreover, the optimization within the prior art condition or through routine experimentation is not considered to be inventive (MPEP 2144.05).

Furthermore, the concentration of arginine being about 15mM is also taught by the '856 patent. The use of arginine in concentration of about 0.5%-5% (col. 4, lines 30-50, in particular). Given the molecular weight of arginine being 174.2g/ml, 2.55% of arginine is equivalent to about 15mM.

In light of the discussion above, the combination of the references remains obvious.

6. The following new ground of rejection is necessitated by Applicants' amendment filed 8/17/07.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-3, 5-7, 25-28, 31-33, 35-37 and 40-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US2003/0113316 A1 in view of U.S. Pat. No. 5,580,856 (of record).

The '316 publication teaches a stable liquid/or lyophilized formulation comprising 50mg/ml IgG2 in 5-25mM of Histidine, 7-55mM serine (Examples 3-4, claims 1-9, in particular) in the presence of polysorbate. The '316 publication further teaches that the antibody being humanized , recombinant or antibody fragments ([0048-0052], in particular).

The claims 25-27, 43 and 45 drawn to "kit" are included in this rejection as the '316 publication teaches that many antibodies are in market are supplied with sterile water for injection ([00067], in particular).

The '316 publication further teaches that histidine buffer contributes less to the osmolarity and suggests to use other stabilizing agents ([0058-0061], in particular).

The '316 publication does not teach use of arginine in concentration of about 15mM as in claim 1.

However, the '856 patent teaches use of arginine in concentration of about 0.5%-5% (col. 4, lines 30-50, in particular) as osmolytes in stabilizing proteins. Given the molecular weight of arginine being 174.2g/ml, 5% of arginine is equivalent to about 15mM. The use of osmolytes is well known in the art by reducing surface interaction or reducing non-covalent interactions of biological molecule and adds stability of protein (col. 4, lines 18-28, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to add arginine as an osmolyte as taught by the '856 patent in the liquid/solid antibody formulation taught by the '316 publication.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '856 patent teaches that an osmolyte such as an arginine adds stability in protein formulation (col. 4, lines 30-52, in particular).

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. No claims are allowable.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
November 7, 2007

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